

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

EARL RINGO JR. et al.)	
Plaintiffs,)	
)	
v.)	09-4095-CV-C NKL
)	
GEORGE A. LOMBARDI et al.,)	
Defendants.)	

**DEFENDANT’S SUGGESTIONS IN OPPOSITION TO
PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT**

Introduction

On August 19, 2010, this Court granted judgment on the pleadings for Defendants on a claim that Missouri’s method of executing murderers, by lethal injection, violates the Controlled Substances Act (CSA) and the Food Drug and Cosmetic Act (FDCA) (Document 138). This Court stated the following. “As to Plaintiffs’ claim seeking a declaratory judgment that the State is violating the CSA and FDCA, the Court grants judgment on the pleadings in favor of Defendants” (Document 138 at 7). This Court, however, considered that the suit might be able to continue as a preemption suit seeking to vindicate the rights of the United States under the Supremacy Clause and held that “it is too soon to proceed with analysis of Plaintiffs’ preemption claims.” (Document 138 at 10). This Court did not address Plaintiffs’ arguments under 42 U.S.C. §1983 because Plaintiffs had not actually raised a claim under 42 U.S.C. §1983, but this Court held that

“anything short of an unambiguously conferred right does not support an individual right of action under §1983” (Document 138 at 12).

Therefore, it has been decided that there is no cause of action under the FDCA or CSA that Plaintiffs could raise and rely on to obtain relief from this Court. The issues remaining in this case are therefore whether Plaintiffs have a cause of action arising under the Supremacy Clause or 42 U.S.C. §1983 through which they can enforce their views of the CSA and FDCA against the State of Missouri because of its status as a State actor, although they could not enforce the statutes against other defendants, whether the Acts are enforceable by Plaintiffs against Defendants under either the Supremacy Clause or 42 U.S.C. §1983, whether the CSA and FDCA preempt State law on executions, whether the conduct challenged by Plaintiffs actually violates the CSA or the FDCA, and whether Plaintiffs have shown a sufficient injury in fact caused by Defendants and correctable by this litigation to have standing .

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Response to Plaintiffs' Statement of Uncontroverted Material Facts

1. Uncontroverted with the exception that Plaintiff Link has now been executed and the case is moot as far as he is concerned. *See Spencer v. Kemna*, 523 U.S. 1 (1998).

2. Uncontroverted.

3. Uncontroverted.

4. Uncontroverted.

5. Uncontroverted.

6. Uncontroverted.

7. Uncontroverted with the caveat that the deposition of M2 at 23-24 reflects that these numbers are approximations.

8. Controverted. The record does not establish that any medical qualification is required to administer the three lethal chemicals during an execution. (This is not established by the quoted statements from M2, an LPN, at 153-155 and 163-164. This paragraph is a legal conclusion.)

9. Uncontroverted.

10. Uncontroverted.

11. Uncontroverted with the exception that M3's current DEA registration has been provided as Defendants' Exhibit 9.

12. Uncontroverted.

13. Controverted. The Clements deposition at 26, and the Lombardi deposition at 53, state that Clements and Lombardi are unaware of any medical training possessed

by NM1 and NM2, not that they necessarily do not have any. The deposition of M3 at 93-94 indicates knowledge of some medical background of one of the nonmedical team members by M3.

14. Uncontroverted with the exception that Tom Clements is no longer the Director of Adult Institutions in Missouri. Clements has accepted a position in Colorado.

15. Uncontroverted.

16. Uncontroverted.

17. Uncontroverted with the addition that, in the dosage given, the sodium thiopental is itself lethal. (Deposition of M3 at 57 stating that 5 grams of sodium thiopental by itself is sufficient to cause death.)

18. Controverted. M3 testified that he was speculating as to the purpose of relaxed muscles created by pancuronium bromide. (Deposition of M3 at 74). M2 did not offer an opinion as to why a muscle relaxant is used beyond stopping respiration. (Deposition of M2 at 145-146). Director Clements stated the purpose of pancuronium bromide as stopping respiration. (Deposition of Clements at 66-67).

19. Uncontroverted.

20. Uncontroverted.

21. Uncontroverted.

22. Uncontroverted.

23. Uncontroverted.

24. Uncontroverted.

25. Uncontroverted.

26. Uncontroverted with the explanation that the drugs are injected into a port in the IV that has been established by the physician as opposed to directly into the inmate.

27. Uncontroverted.

28. Uncontroverted.

29. Uncontroverted.

30. Uncontroverted.

31. Uncontroverted.

32. Uncontroverted.

33. Uncontroverted.

34. Controverted. The page cited by Plaintiffs says nothing about “painful” suffocation. (Deposition of M3 at 58). The characterization “painful” appears to be Plaintiffs’ editorial comment.

35. Controverted. The deposition says “when you stop the heart they would probably have chest pains like a heart attack.” (Deposition of M3 at 58).

36. Uncontroverted with the addition that the 5 gram dose of thiopental is itself lethal. (Deposition of M3 at 57).

37. Controverted. M3 agreed putting the offender to sleep is a medical purpose. (Deposition of M3 at 55). Director Lombardi does not state at pages 93-94 of his deposition that thiopental is given for a medical purpose. It is a mischaracterization of the testimony to represent the administration of a lethal dose of chemicals during an execution as a medical procedure because the chemicals are administered in a way that

minimizes potential discomfort. (See deposition of M3 at 57 noting that the maximum dose of thiopental used as anesthesia is 1/10th the dose used in an execution.)

38. Uncontroverted only in so far as this is one of the reasons the anesthesiologist participates in executions. (See deposition of M3 at 104 stating that to ameliorate or relieve possible suffering is “one of the roles” of the anesthesiologist).

39. Controverted. This paragraph is misleading. M3 was asked, “Well for the period of time that you’re working with him and administering drugs and doing other things to relieve pain and suffering, you’re their doctor, correct?” (Deposition of M3 at 112). After, he said, “That’s correct”, the next statement by counsel was “Let’s return to the execution.” (Deposition of M3 at 113). Read in context, the doctor’s testimony was not that the execution itself is a medical proceeding with the physician acting as the offender’s doctor.

40. Controverted. Page 152 of the deposition of M2 does not contain the quote cited. At page 152 the nurse is asked the duties of LPNs under state law and as taught in nursing school.

41. Uncontroverted.

42. Uncontroverted with the exception that the only drug that M2 would possibly dispense would be one or two oral valium tablets that the offender has the option of taking on the evening of the execution.

43. Uncontroverted with the caveat that the nurse is talking about providing comfort and reassurance before the execution, not about the actual execution itself. (See

deposition of M2 at 173 stating, “No, ma’am, I’m not executing them,” after the discussion of the offender being a patient).

44. Controverted. Defendants do not admit that a criminal being executed is a patient in the normal sense of the word.

45. Uncontroverted

46. Uncontroverted.

47. Uncontroverted.

48. Uncontroverted.

49. Controverted as to the phrase medically therapeutic. That characterization does not appear to be in the cited testimony of M2 or M3.

50. Uncontroverted.

51. Uncontroverted.

52. Uncontroverted with the understanding that the paragraph refers to a pre-execution sedative.

53. Uncontroverted.

54. Uncontroverted in the sense that it is not an over-the-counter medication that may be purchased by the end user without a prescription in a normal context.

55. Uncontroverted in the sense that it is not an over-the-counter medication that may be purchased by the end user without a prescription in a normal context.

56. Uncontroverted.

57. Uncontroverted.

58. Uncontroverted.

59. Uncontroverted.

60. Uncontroverted with the caveat that M3 indicates in his deposition that one of the nonmedical personnel had some medical experience in a former job. (Deposition of M3 at 93-94).

61. Uncontroverted.

62. Uncontroverted.

63. Controverted. At page 155 of his deposition, M3 testifies that after each practice the Director asks him if the nonmedical personnel were pushing correctly, and that if they were not, "I think I would probably tell them either to pick it up a little bit or back off a little bit." (Deposition of M3 at 155). (See also deposition of M3 at 126, discussing practicing the injection rate with a timer to achieve the proper rate).

64. Uncontroverted.

65. Uncontroverted.

66. Uncontroverted in part, in so far as the testimony indicated a vein could rupture causing a chemical not to reach its destination. The comments about possible failure of the thiopental to induce unconsciousness do not seem to be in the portion of the record cited in the paragraph. The testimony about an intramuscular injection of thiopental burning was in the context of an inquiry from a physician in another state concerning whether the execution chemicals could be injected intra-muscularly, to which M3 replied no because they burn. (Deposition of M3 at 39-40).

67. Uncontroverted.

68. Uncontroverted with the qualification that M2's testimony appears to indicate that M2 would inject normal saline when ordered by a physician but would not consider it to be an IV push because the content was saline as opposed to a medication. (Deposition of M2 at 47-48).

69. Uncontroverted.

70. Uncontroverted.

71. Uncontroverted in a medical treatment context. Defendants do not agree that an execution by lethal injection is a medical treatment requiring medical personnel to administer the lethal chemicals.

72. Uncontroverted.

73. Uncontroverted in the context of medical treatment. Defendants do not agree that an execution by lethal injection is a medical treatment requiring medical personnel to administer the lethal chemicals.

74. This is a legal conclusion not a statement of material fact. M2 was asked if he would be willing to remain on the execution team if he were required to actually administer the lethal chemicals and he replied, "I would not be able to do that due to my licensure." (Deposition of M2 at 163).

75. Uncontroverted.

76. Uncontroverted.

77. Controverted. Since the Plaintiffs motion for summary judgment was filed, one practice using ten grams of thiopental and one execution involving the drawing up of

ten grams of thiopental occurred. The stock has been reduced from fifty grams to thirty grams.

78. It is uncontroverted that the practice on October 12, 2010, did not use actual thiopental. Since then, a practice on January 23, 2010 sing thiopental, and an execution, in February 2010, have occurred.

79. Uncontroverted with the addition that the FDA does not approve drugs for use in lethal injection.

80. Uncontroverted.

81. Controverted. It is clear from M3's deposition that he was unfamiliar with the term "off label use," associating it with "using it when it's not for a purpose." (Deposition of M3 at 59). When asked if he knew if a prescription was required for off label use, he said he could not answer because he did not know what the questioner meant by off label use. (Deposition of M3 at 62). M3 testified that in his practice he does not write a prescription for an anesthesia drug because it is administered by himself or someone under his direct control. (Deposition of M3 at 70-72).

82. Uncontroverted.

83. Uncontroverted.

84. Uncontroverted.

85. Uncontroverted.

86. Uncontroverted.

87. Uncontroverted.

88. Uncontroverted.

- 89. Uncontroverted.
- 90. Uncontroverted.
- 91. Uncontroverted.
- 92. Uncontroverted.

Congress intended the CSA and FDCA to be enforced only by the Federal Executive Branch and this cuts off any private right of action even under the Supremacy Clause or 42 U.S.C. § 1983.

In granting partial judgment on the pleadings for Defendants, this Court, agreeing with *Durr v Strickland*, Slip op. 2:10-cv288, 2010 WL 1610592 (S.D. Ohio, April 15, 2010) *aff'd* 602 F.3d 788 (6th Cir. 2010) found that this action is an improper attempt to privately enforce the FDCA and the CSA, and found “As to Plaintiffs’ claim seeking a declaratory judgment that the State is violating the CSA and the FDCA, the Court grants judgment on the pleadings for the Defendants.” (Document 138 at 3). But this Court allowed the case to continue on the issue of whether Plaintiffs make out a claim for preemption of Missouri’s execution statute or protocol by Federal law finding that the question “is not properly decided on a motion for judgment on the pleadings.” (Document 138 at 5).

Recent challenges to State execution by lethal injection procedures, as violating the FDCA and the CSA, have been rejected by the United States District Court for the Southern District of Ohio and the United States Court of Appeals for the Sixth Circuit in *Durr v. Strickland*, by the Supreme Court of Washington in *Brown v. Vail*, 263 P.3d 263 (Wash. 2010); by the United States District Court for the Western District of Washington in *Brown v. Vail*, Slip op. C-09-5101 (W.D. Wash. Aug. 31 2010), by the United States District Court for the Eastern District of Kentucky in *Bowling v. Haas*, Slip Op. 3: 07-032KKC 2010 WL 32825467 (E.D. Kentucky Sept 23, 2010), by the United States District Court for the Eastern District of Arkansas in *Jones v. Hobbs*, Slip. Op. 5:10-cv-0065 JLH 2010 WL 2985502 (E.D. Ark. July 26, 2010), by the United States District

Court for the Middle District of Tennessee in *West. v. Ray*, Slip op. 3:10-0778 (M.D. Tenn. Sept. 24, 2010), and by the Supreme Court of Tennessee in *Tennessee v. Harbison*, Slip op. M1986-00093-SC-OT-DD (Tenn. Oct 12, 2010)(per curiam)(denying petition for rehearing on an order to set execution date, alleging Tennessee execution procedures violate the FDCA and CSA).

The key principle that links these cases together is that Congress intended the Acts to be enforced only by the Federal Executive, and Congress made no exception from that intention for what are in reality private enforcement actions against State actors by private individuals. There is no truly plausible way to distinguish cases such as *Durr*, *Jones*, *Brown*, *Bowling*, and *West* from this case. If the courts in those cases accepted the analysis that those cases could have continued under a preemption theory, the cases would have continued. But they did not continue. In *Bowling* the district court, described this case (*Ringo*) as “an action involving identical claims” (*Bowling* at 3), noted that *Bowling* relied on the Supremacy Clause (*Bowling* at 5), and found that the question of whether a State actor had complied with these statutes must be asked by Federal law enforcement officials in the first place (*Bowling* at 6). The district court in *West* acknowledged that this Court allowed this case to continue on the theory that the claim hinged on the supremacy of Federal law rather than individual rights but found that the courts in the *Jones* and *Durr* cases did not make that distinction and concluded that letting the case continue would “evade the intent of Congress” and “circumvent the discretion entrusted to the executive branch” *West* at 3-4). The clear intent of Congress that the FDCA be enforced by the FDA and not private citizens and that the CSA, a

statute with criminal penalties, be enforced by the Attorney General, cuts off any cause of action by individuals under a preemption theory against State officials just as it does other private actions to enforce the statutes. Similarly, in order for a cause of action under 42 U.S.C. § 1983 to exist Congress must have intended such a private right of action to exist. *Lankford v. Sherman*, 451 F.3d 496, 508-509 (8th Cir. 2006). Congressional intent cuts off a private right of action under the Supremacy Clause and 42 U.S.C. § 1983.

The plain statement rule governs and, cuts off this cause of action because the execution of criminals under State law is not an area traditionally regulated by Congress.

Additionally, the intention of Congress to regulate executions would be an exercise of control over an area traditionally reserved for State authorities and would alter the usual balance between the States and the Federal Government. In such a case the intention of Congress to exercise control over the area traditionally left to the States must be unmistakably clear or it is presumed not to exist. *See Oregon v. Ashcroft*, 368 F3d 1118, 1124-1125 (9th Cir. 2004) (applying the plain statement rule standard of unmistakable clarity to reject a claim that Congress intended that the CSA could be used to regulate physician assisted suicides using controlled substances even though physician assisted suicides are permitted by Oregon law) *aff'd Gonzalez v. Oregon*, 546 U.S. 243,274 (2006) (Supreme court finds that applying prescription requirements of CSA to ban physician assisted suicides would intervene in an area traditionally reserved to the States but that it was unnecessary to reach the level of analyzing “clear statement requirements” to reject the claim that the statute authorizes a ban on physician assisted suicide) ; *See also Gregory v. Ashcroft*, 501 U.S. 452, 460-461(1991)(applying the

unmistakable clarity standard to reject the idea that the Age Discrimination in Employment Act applies to State judges in the face of a State statute mandating judicial retirement at age 70); *Nixon v. Municipal League*, 541 U.S. 125 (2004) (using the plain statement requirement of unmistakable clarity in rejecting a claim that the term “any entity” in the Telecommunications Act of 1996 included municipalities that sought to provide telecommunications services contrary to Missouri law). The plain statement rule controls in the area of Constitutional executions of criminals by the States, because that area has traditionally been left to the States by Congress, and there is no plain statement in the CSA or the FDCA that those Acts are meant to regulate executions by lethal injection. The analysis by the Ninth Circuit Court of Appeals in *Oregon v. Ashcroft* rejecting a claim that the CSA could be used to regulate or prohibit physician assisted suicide is particularly instructive. *See Oregon*, 368 F.3d at 1125(finding that unless the authorization by Congress is “unmistakably clear” the Attorney General cannot exercise control under the CSA over an area traditionally reserved for state authority and that Congress has provided no unmistakably clear indication it intended the Attorney General to be able to use the CSA to regulate physician assisted suicides). *See Id.* at 1126 (stating that physician assisted suicide is an unrelated general medical practice to be regulated by state law makers in the first instance and that “We know Congress intended to limit federal authority under the CSA to the field of drug abuse”). It is illogical that Plaintiffs have a cause of action that survives only because it is brought against State actors, when the plain statement rule would bar the officials charged with enforcing the statute raising the same claim against the same Defendants. The same bar applies to Plaintiffs. The

lack of a plain statement by Congress that it intended the FDCA & CSA to be enforced in the context of executions for State criminal convictions, an area traditionally left to the States by Congress, reinforces the conclusion that Plaintiffs have no cause of action to pursue.

But even without the plain statement rule, the clear intent of Congress that the Acts be enforced only by the Federal Executive would cut off a preemption suit that seeks to enforce the Acts against State officials as well as suits against private individuals, as that intent is clear from the Acts themselves. Defendants will now analyze the case in the context of Eleventh Amendment immunity. But even absent Eleventh Amendment immunity, the analysis would reach the same result as the cases cited above rejecting identical or similar claims.

Sovereign immunity cuts off this cause of action.

Defendants have asserted and continue to assert Eleventh Amendment immunity from suit in this case (Document 148). The *Ex Parte Young* exception to Eleventh Amendment immunity, for claims alleging a conflict between State and Federal law seeking, only prospective relief, is itself subject to exceptions. Those exceptions include cases in which a “federal statutory scheme evidences an implicit or explicit intent to exclude *Ex Parte Young* actions” and cases in which “the suit and remedy implicate special sovereignty interests such that an *Ex Parte Young* action will not lie.” *Union*

Electric Company v. Missouri Department of Conservation, 366 F.3d 655, 658 (8th Cir. 2004).¹

The analysis under the first exception is not whether Congress intended to exclude all *Ex Parte Young* actions under the statutory scheme but rather whether Congress intended to exclude the particular type of *Ex Parte Young* action in the case before the court. *Id.* at 658. In *Union Electric* the Missouri Department of Conservation sued a utility company in State court for 3.256 million dollars in damages that resulted from a fish kill. The utility company brought a suit for declaratory and injunctive relief in Federal court alleging that any State court or administrative actions to impose liability were preempted by the Federal Power Act. The United States Court of Appeals found that the Act by stating that licensees were liable for damages to the property of others without making a distinction based on whether the damaged parties were private individuals or States demonstrated intent that *Ex Parte Young* actions could not be brought seeking to prevent States from recovering damages. *Id.* at 658. In short *Ex Parte Young* could not be used to do an end run around the intent of Congress by attempting to maintain against a State a type of suit that it was contrary to the intent of Congress for the plaintiffs to maintain against any defendant. But that is exactly what Plaintiffs in this case are attempting to do.

¹ The first exception arose in *Seminole Tribe of Florida v. Florida*, 544 U.S. 44, 74-75 (1996), a case in which the Court took the provision of a comprehensive enforcement scheme targeted at the states as evidence of intent that Congress had not meant to authorize *Ex Parte Young* suits for the same enforcement purpose.

The Food Drug and Cosmetic Act provides a detailed remedial scheme and specifically states that proceedings to enforce or restrain violations of the Act “shall be by and in the name of the United States.” 21 U.S.C. §337. The statute makes no exception for a case where a State or State official is a proposed defendant. The type of suit Plaintiffs are bringing in this case, like the suit in *Union Electric* is contrary to the intent of the Act and is futile. It is difficult to see how Congress could have made its intent to bar private attempts to restrain alleged violations of the FDCA any clearer. Such suits by private individuals are explicitly banned regardless of who the defendant is, and whether or not the relief sought is prospective. And allowing such suits to proceed is contrary to the intent of Congress. Therefore the suit cannot breach Eleventh Amendment immunity under *Union Electric* and *Seminole Tribe*, whether or not it is called a preemption action and the defendant is a State official, because it is the intent of Congress that such actions not occur at all.

Similarly, the CSA also provides a detailed remedial scheme for alleged violations of that Act, to be enforced by the Attorney General of the United States with sanctions including actions against registrations, fines, and criminal penalties. *See* 28 U.S.C. §§ 821, 824, 844-846. The statute makes no distinction permitting private enforcement against State actors. The key question for analysis under *Union Electric* is the intent of Congress not to permit the type of *Ex Parte Young* suit that is being prosecuted. The structure and provisions of the statute evidence Congressional intent not to permit the type of *Ex Parte Young* actions that Plaintiffs bring in this case. It is Congressional intent that is critical. The structure and provisions of the statute are only the evidence of that intent. As with

the FDCA, the presence of a detailed remedial scheme to be enforced exclusively by the Federal government in the CSA and FDCA is simply inconsistent with the existence of *Ex Parte Young* suits that are in reality private enforcement actions against the States. Such suits cannot breach the immunity of the several states to suit under the Eleventh Amendment to the United States Constitution.²

Additionally, the plain statement rule of *Oregon v. Ashcroft*, *Gregory v. Ashcroft*, and *Nixon v. Municipal League* should also have a role in Eleventh Amendment analysis. Although Defendants prevail under *Union Electric* and *Seminole Tribe* based on the clear intention of Congress that the Acts not be privately enforced against anyone, without using the plain statement rule, the plain statement rule also cuts strongly against there being Congressional intent to enforce the CSA and FDCA through *Ex Parte Young* actions in the case of State executions, an area traditionally within the regulation of the Several States and in which regulation would represent a shift in the traditional balance of Federal/State responsibility. Therefore the plain statement rule is a sufficient but not necessary means of establishing immunity from an *Ex parte Young* suit under the exception described in *Union Electric* and *Seminole Tribe*.

² The clear intent of Congress not to permit what are in essence private enforcement actions of the CSA and FDCA should in Defendants' view prevent such actions regardless of whether the defendant is a State official attacked under a nominal preemption theory or a 42 U.S.C § 1983 theory and regardless of whether Eleventh Amendment immunity is asserted. Similar suits were cut off in *Durr v. Strickland*, *Jones v. Hobbs*, and *Brown v. Vail*, *Bowling v. Haas*, and *West v. Ray* without the necessity of reliance on Eleventh Amendment immunity. But Defendants assert Eleventh Amendment immunity, and under *Union Electric* and *Seminole Tribe* that assertion also should end the case.

The suit fails as a preemption action because in conducting preemption analysis it is assumed Congress did not intend to preempt an area traditionally regulated by the States.

In *Wyeth v. Levine*, 129 S.Ct. 1187 (2009) the United States Supreme Court rejected a claim that the FDCA preempted State law on the labeling of medicine in the sense that approval of a label by the FDA did not protect a drug manufacturer from damage suits under State law for inadequate labeling. The Supreme Court pointed out that the intention of Congress is the touchstone of preemption analysis and that where Congress has legislated in a field traditionally occupied by the States analysis starts with the assumption that the historic police powers of the states were not superseded by the Federal Act, unless that was the clear and manifest purpose of Congress. *Id.* at 1194-1195. The Court held that the fact the United States had regulated drug labeling for over a century did not overcome the presumption against preemption, which is based on respect for the States as independent sovereigns. *Id.* at 1195 n.3.

The Court held that if Congress had really thought that that State law suits on drug labeling posed an obstacle to the objectives of the Act, Congress would have enacted an express preemption provision sometime during the seventy year history of the FDCA. *Id.* at 1200. The reasoning of *Wyeth* is instructive. It must be presumed that Congress did not intend the CSA and FDCA to preempt State law on carrying out the execution of State criminals, an area traditionally occupied by the States, and it also must be presumed that if Congress really viewed the purpose of the FDCA and CSA as including the regulation of executions it would have expressly said so in the decades that the United States and the Several States have carried out executions by lethal injection. *See also*

Delaware v. Deputy, 644 A.2d 411, 417-420 (1994)(conducting similar analysis specifically in the context of the CSA, FDCA and execution by lethal injection).

The FDA and CSA are not properly enforced through 42 U.S.C. § 1983.

In *Lankford v. Sherman*, 451 F.3d 496 508-509 (8th Cir. 2006) the United States Court of Appeals held that for an Act to be able to support a cause of action under 42 U.S.C. § 1983 “the statute must focus on an individual entitlement to the asserted federal right, rather than on the aggregate practices or policies of a regulated entity like the state.” The FDCA and CSA focus on the conduct of regulated entities rather than on individual entitlements to Federal rights and simply do not qualify as the type of Acts that could support a § 1983 suit.

The actions about which Plaintiffs complain do not violate the CSA or FDCA.

Plaintiff’s Count 1 is an assertion that that the CSA will be violated because controlled substances will, in the process of an execution by the State, allegedly be obtained and administered without a prescription by someone other than a licensed medical professional in violation of 21 U.S.C. 822(a) and 21 U.S.C. 829(b). (Amended Complaint at 23-24). In *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006) the United States Supreme Court set out the main objectives of the CSA as combating drug abuse, and controlling the legitimate and illegitimate traffic in controlled substances. The Court found that read in context the prescription requirement is a “is a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse....As a corollary, the provision also bars doctors from

peddling to patients who crave drugs for those prohibited uses.” *Id.* at 274. The Court concluded that the use of prescription drugs in physician assisted suicides is not “drug abuse” banned by the statute. *Id.* The Court stated that “we conclude the CSA’s prescription requirement does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct.” *Id.* at 274-275. The Court also noted that this was an area traditionally regulated by the States but that it is “unnecessary to even consider the application of the clear statement requirements.” *Id.* at 274. *Gonzalez v. Oregon* is on point. Plaintiffs are essentially reading provisions of the CSA out of context in order to find violations from conduct that is not banned by the statute, and it is not necessary to reach the level of analyzing plain statement requirements, as the Ninth Circuit Court of Appeals did in *Oregon v. Ashcroft*, to be firmly convinced of that conclusion. But to reach the opposite conclusion, that the claim has merit, the claim would have to withstand plain statement analysis and preemption analysis that assumes Congress did not intend to preempt an area traditionally occupied by the States. It cannot. Count one fails on the merits as a matter of law based on both the test of the statute read in context, and based on the use of plain statement rule as a tool of statutory interpretation. As the United States Supreme Court pointed out in *Gonzalez v. Oregon*, the prescription requirements of the CSA are meant to prevent addiction, recreational abuse and peddling drugs to addicts and recreational users. Just as those provisions do not authorize using the Act to regulate physician assisted suicides, they do not authorize the regulation of executions by the Several States.

Plaintiffs Counts 2 and 3 are based on alleged violations of the FDCA, by the use of chemicals in executions by lethal injection by non-medical personnel without a prescription, by the adding of saline solution to a sodium thiopental powder by a board certified anesthesiologist instead of a pharmacist, and by using chemicals not approved by the FDA for use in lethal injections without a prescription for off label use. The portion of the FDCA dealing with prescriptions is in a section defining dispensing a drug that is safe for use only under the supervision of a physician, without a prescription, as a type of the prohibited conduct of misbranding a drug while holding it for sale. *See* 21 USC 353 (b)(1). This provision read in context has absolutely nothing to do with the conduct Plaintiffs are complaining about. It is a provision aimed preventing dispensing prescription drugs to consumers as over the counter medication i.e. misbranding while holding for sale. Reading the statute in context makes clear that this provision is not applicable to executions by lethal injection. There is no possible way to interpret the use of chemicals in a lethal injection as misbranding the chemicals while holding them for sale, the conduct actually banned by the allegedly relevant provision of the Act.

Similarly, it is difficult to see how a board certified anesthesiologist violates the FDCA by adding saline solution to an anesthetic powder in order to draw it up in a syringe. Plaintiffs do not assert what provision of the statute is allegedly violated by that conduct. But it strains plausibility that a physician is required to stop what he is doing and call in a pharmacist every time he adds saline solution or water to a powdered medicine in order to draw it up in a syringe.

Finally, Plaintiffs allege that the FDCA is violated because the chemicals not approved for use in lethal injections by the FDCA are used in lethal injections and the physician does not write a prescription for this off label use. Plaintiffs appear to rely on the same section of the Act about misbranding drugs while holding them for sale. The FDA does not approve chemicals use in lethal injections. *See Heckler v. Chaney*, 470 U.S. 821, 824-825 (1985). Therefore the only way to comply with Plaintiffs' reading of the statute would be for the physician to write a prescription. But writing a prescription for an item used in a lethal injection in the physician's presence would be a pointless act. It would neither prevent misbranding while holding a drug for sale nor inhibit recreational drug use. *See Gonzalez v. Oregon*, 546 U.S. at 274 (explaining the point of prescription requirements). The conduct complained of does not plausibly violate any provision in the CSA or FDCA.

Further, the FDCA, like the CSA, contains no plain statement that it is intended to regulate to Constitutional executions by the Several States. Like the use of controlled substances in physician assisted suicides discussed in *Gonzalez v. Oregon*, and *Oregon v. Ashcroft*, the use of controlled substances, in executions, cannot be viewed as regulated by the FDCA absent a plain and unmistakable statement that such was the intention of Congress. And no plain statement exists. The fact that the FDA itself does not view the statute as controlling in the context of executions is strong evidence that there is no plain statement that Congress intended the statute to regulate execution by lethal injections. Further, as the United States Supreme Court noted in *Wyeth*, in the context of drug labeling, if Congress had really wished preempt an area traditionally occupied by the

States it must be presumed it would have explicitly said so during the long history of the Act. The fact that Congress never explicitly linked the Act to executions, despite the long history of the Act and the long history of execution by lethal injection, as in *Wyeth* is indicative of the intent of Congress not to preempt.

Counts 2 and 3 fail as a matter of law both based on an in context reading of the text of the FDCA itself and on such a reading done in light of the plain statement rule.

Standing

The irreducible Constitutional minimum for a plaintiff to have standing to pursue a case in a Federal court is that the plaintiff has suffered an injury in fact fairly, traceable to the challenged action of the defendant, and it must be likely that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-56 (1992). To be an injury in fact an injury must be an invasion of a legally protected interest which is concrete and particularized, and actual or imminent as opposed to conjectural or hypothetical. *Id.* 560. The party invoking federal jurisdiction bears the burden of establishing these elements. *Id.* at 561.

Plaintiffs' factual complaint in count 1 reduces to the complaint that the anesthesiologist hands the syringe containing sodium thiopental to the person who injects the chemical into a port in the IV while the anesthesiologist observes but the anesthesiologist does not write a prescription before handing the syringe to another person, and that the nurse offers the offender a valium tablet for which the physician does not write a prescription (Amended Complaint at 23-24). Assuming for the sake of argument that this conduct can be plausibly characterized as a violation of 21 U.S.C. §

822(a) or 21 U.S.C. §829, which is at best a questionable proposition, and assuming that the Controlled Substances Act has any application at all in the context of executions, also a questionable proposition -*See Gonzales v. Oregon*, 546 U.S. 243, 272 (2006) (noting, in rejecting an attempt to use the CSA to prevent the use of controlled substances in legal assisted suicides, that the CSA is “a statute combating recreational drug use”)-, Plaintiffs still must show that they suffer an injury in fact in order to challenge the alleged violations of the statute.

Plaintiffs cannot show an actual or imminent, concrete, and particularized invasion of a legally protected interest of Plaintiffs in the fact pattern of this case. Plaintiffs do not suffer an injury in fact because the anesthesiologist does not write a prescription for the nurse to offer to dispense a valium tablet, or for the person who pushes the plunger on the syringe in the IV port to push the plunger, nor because the chemicals are bought by the institutional business manager as opposed to by the physician personally. If the physician wrote a prescription no injury would be averted that occurs because he does not do so. It cannot be plausibly argued that the law requires that every execution be carried out by a physician, which is the implicit premise of Plaintiffs’ argument, with the alleged injury being execution by a non-physician. There is no legally protected interest in being executed by a physician and therefore no injury in fact happens when Plaintiffs are not executed by a physician.

. Count 2 is a similar claim, but based on the Food Drug and Cosmetic Act (FDCA). Plaintiffs challenge the administration of the actual execution drugs sodium thiopental, pancuronium bromide, and potassium chloride without a prescription as well as the

potential use of ketamine, midazolam, heparin (an anti-coagulant), romazicon (an antidote to certain sedatives such as valium), lidocaine (a numbing agent) and methylene blue (a blue dye) (Amended Petition at 24-25). Plaintiff alleges these chemicals will be administered by “non-medical personnel” (Amended Petition at 24-25). Further Plaintiffs allege that one or more drugs including sodium thiopental is mixed, compounded or prepared by someone other than a pharmacist and that this violates the FDCA.

The actions prohibited by the FDCA are listed at 21 USC §331. Title 21 USC §331(k) bars altering or misbranding a food, drug or cosmetic while holding it for sale. Another provision, 21 USC 353(b)(1) describes dispensing a drug that is only safe for use under the supervision of a licensed medical practitioner as a form of misbranding a drug while holding it for sale. That was the provision alleged to be violated by lethal injection in the *Cheney v. Heckler* litigation. *See Chaney v. Heckler*, 718 F.2d 1174, 1199 (D.C. Cir. 1983) (Scalia J. dissenting)(stating, referring to drugs used in executions by lethal injection, “under no conceivable interpretation of the English language could they be deemed held for sale”). Assuming for the sake of argument that the FDCA has any application to executions by lethal injection which it probably does not –*See Heckler v. Chaney*, 470 U.S. 821, 824-825 (1985) (FDA Director opines the Agency probably does not have jurisdiction over executions)-, and assuming that some provision of the FDCA can somehow be read to be violated by Missouri executions, Plaintiffs still must show an injury in fact to have standing to challenge the alleged violation.

Plaintiffs cannot show an injury in fact. The only chemicals administered by non-medical personnel are the sodium thiopental, pancuronium bromide, and potassium

chloride –a syringe of saltwater used to flush the line is also injected by non-medical personnel (Exh. 4 “Preparation and Injection of Chemicals”; Exh. 5 Training Manual). The extent of the administration by non-medical personnel is that these chemicals are injected from already prepared syringes into an injection port on the IV tube under the observation of the anesthesiologist (Exh. 2 at 120-121). The sodium thiopental is the only chemical mixed and the mixture consists of the anesthesiologist adding saline solution (salt water) to vials of sodium thiopental powder (Exh. 2 at 88-92). The extent of any potential injury in fact to Plaintiffs therefore must necessarily arise either from the anesthesiologist mixing the sodium thiopental with saline solution, as opposed to having a pharmacist do it for him, or from the non-medical personnel injecting sodium thiopental without a prescription, pancuronium bromide, and potassium chloride into the IV portal while being observed by the anesthesiologist, rather than the anesthesiologist pushing the plunger himself. A prescription does not make the process safer, and the actual pushing of the plunger is done under the observation of the anesthesiologist by persons trained to do that task. Plaintiffs have no legally protected interest in being executed by a physician and therefore suffer no injury in fact when this does not occur.

In Count 3 Plaintiffs allege that an unspecified provision of the FDCA is violated because the chemicals used in lethal injections although allegedly approved for use by the FDA are not approved for use in lethal injections and the physician does not write a prescription for their use in this manner (Amended Complaint at 25-26). The FDA does not approve chemicals for use in executions by lethal injection viewing that activity as outside its function. *See Heckler v. Chaney*, 470 U.S. 821, 824-825 (1985); “FDA takes

Stance on the Importation of Lethal Injection Drugs” <http://swsj.com/law/2011/01/04>).

Therefore assuming for the sake of argument that the FDA is wrong in believing the FDCA does not regulate lethal injections, and that the use of chemicals in the lethal injection process without FDA approval for their use in lethal injections somehow violates the FDCA, Plaintiffs still must show an injury in fact traceable to Defendants and likely to be resolved by a favorable decision.

There is no injury in fact to Plaintiffs because the chemicals used in the lethal injection procedure are not approved by the FDA for use in lethal injections. Plaintiffs have not alleged any evidence exists, and cannot establish, that they are actually harmed in any way because the chemicals used in lethal injections are not approved by the FDA for that purpose, and are used without a prescription. If the physician were to write a prescription for an off label use that would not have any practical effect on Plaintiffs, and the lack of a prescription causes no injury. Further, because the FDA is not in the business of approving chemicals for use in lethal injections, and there is no reason to believe it will ever be in that business, any alleged harm from the failure to use chemicals approved for use in lethal injections is not traceable to Defendants, and cannot really be remedied by a favorable judicial decision in this case.

Conclusion

Summary judgment should not be granted for Plaintiffs and should in fact be granted for Defendants. In essence Plaintiffs are taking statutes that were never intended to have anything to do with State executions, an area traditionally regulated by the Several States, and complaining that the square pegs of execution procedures do not fit

snugly in the round holes of provisions of the statutes meant to deal with something entirely different. Plaintiffs ignore the overall context of the provisions of the statutes that they allege are violated. This is exactly the type of analysis the United States Supreme Court criticized in *Gonzalez v. Oregon* in rejecting the theory that the prescription provisions of the CSA can be used to prevent physician assisted suicides. Plaintiffs' Counts 1, 2 and 3 all fail because the conduct complained of does not violate the FDCA or the CSA, as well as due to lack of standing, lack of Congressional intent that there may be may private actions to enforce these Acts, lack of preemption of State law in the field of executions by lethal injection, lack of a cause of action under 42 U.S.C § 1983 under these Acts, and because of sovereign immunity.

Respectfully submitted,

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Certificate of Service

I hereby certify that a true and correct copy of the foregoing document was filed electronically on February 14, 2011 and should be served electronically on counsel for all Plaintiffs.

/s/Michael J. Spillane